REMARKS

Claims 34 and 36-69 are pending in this application. Claims 1-33 and 35 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 38-69 have been newly added. Claims 33, 35 and 36 have been withdrawn as being directed to non-elected subject matter.

Applicants thank the Examiner and his supervisor for their willingness to conduct the interview with Applicants' representatives on December 9, 2009 and discuss potential claim amendments for overcoming each rejection in the pending Official Action. During the interview, the Examiner indicated his thought that it would be very helpful to further amend the claims to include structural limitations regarding the particles and/or to recite the amount of bioresorption of the ceramic particles and the time required for the same in an effort to further distinguish the claims from the cited references. According to the Examiner's indication, presented herein are new claims incorporating the limitation, "said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months."

In particular, newly added claim 38 corresponds to cancelled claim 17 and further limits i) the implant to be "resorbable," ii) the microparticle to be "biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months," and iii) the ceramic compound to be "βTCP" only and have a "specific surface area of from 0.5 m^2/g to 100 m^2/g." Claims 39-54 are directly

or indirectly dependent from claim 38. In addition, newly added claim 55 corresponds to cancelled claim 17 and further limits i) the implant to be a "resorbable," ii) the microparticle to be biodegradable, once the implantation has been made into the fibrous tissue, within a "period of from 2 to 36 months" and to be present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%, and iii) the ceramic compound to be "βTCP" only. Claims 56-69 are directly or indirectly dependent from claim 55.

Support for the amendments can be found throughout the specification and the claims as originally filed, including, for example, page 8, 3rd paragraph and page 13, 2nd paragraph of the specification.

The amendments to and cancellation of the claims are solely for advancing prosecution. Applicants, by amending or cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert the original claim scope of any claim amended herein, in a continuing application.

No new matter has been introduced to this application within the meaning of 35 U.S.C. §132.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 14-16 and 32 were rejected under 35 U.S.C. §112, 2nd paragraph for indefiniteness.

Applicants submit that claims 14-16 and 32 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. None of the newly added claims contains a broader and a narrower range for the same element.

Withdrawal of this rejection is, therefore, respectfully requested.

II. At page 4 of the Official Action, claims 14-16 are rejected under 35 U.S.C. §102(b) as being anticipated by Agerup (US Patent No. 5,633,001).

As aforementioned, claims 14-16 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. No corresponding claims thereto have been added in this application.

Withdrawal of this rejection is therefore respectfully requested.

III. At page 5 of the Official Action, claims 17-21, 24-26, 29-31 and 35 are rejected under 35 U.S.C. §102(e) as being anticipated by Hubbard et al. (US Patent No. 7,060,287).

Applicants traverse this rejection. The test for anticipation under 35 USC §102 requires that a single prior art reference describe each and every element of the claimed invention. *See Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

In the present application, rejected claims 17-21, 24-26, 29-31 and 35 have

been cancelled. Newly added claim 38 corresponds to cancelled claim 17 and contains additional limitations, which recites "A ***resorbable*** implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid, wherein said microparticles are ***biodegradable***, once the implantation has been made into the fibrous tissue, within a period of ***from 2 to 36 months*** and have a size of from 10 to 80 μm, said ceramic compound being ***tricalcium phosphate (βTCP)*** and having a specific surface area of from 0.5 m^2/g to 100 m^2/g, and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties." Claims 39-54 are directly or indirectly dependent from claim 38.

In addition, new claim 55 corresponds to cancelled claim 17 and contains additional limitations, which recites "A ***resorbable*** implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid, wherein said microparticles are ***biodegradable***, once the implantation has been made into the fibrous tissue, within a period of ***from 2 to 36 months*** and have a size of from 10 to 80 μm and are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%, said ceramic compound being ***tricalcium phosphate (βTCP)***, and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with

pseudoplastic properties." Claims 56-69 are directly or indirectly dependent from claim 55.

Accordingly, all of the pending claims in the present application necessarily require a "resorbable implant" comprising microparticles of βTCP which are biodegradable in the fibrous tissue within 2 to 36 months.

Hubbard et al.

Hubbard et al. describes a permanent, biocompatible material for soft tissue augmentation comprising a matrix of smooth, round, substantially spherical particles of a biocompatible ceramic material, where the ceramic material can be homogeneously suspended in a biocompatible, resorbable lubricious gel carrier comprising a polysaccharide. *Hubbard et al.* generally describes βTCP as a potential ceramic material that can be contained in the implant compositions disclosed therein, and each of hyaluronic acid and xanthan gum as a potential polysaccharide that can be added to the composition.

However, as already discussed in the present specification as originally filed, *See* page 5 of the PCT publication (WO 2004/069090), the implant of *Hubbard et al.* has a "***permanent***" nature, preferably employing "hydroxyapatite (HAP)." In this regard, *Hubbard et al.* teaches that since HAP is highly compatible to the tissue and substantially nonresorbable, it makes the ceramic augmentation material permanent and repetitious corrections are not necessary in the implant disclosed therein. *See Hubbard et al.*, col. 4, line 22 and col. 5, lines 47-52. In contrast, the presently

claimed implant is almost totally "***bioresorbable***" comprising as a ceramic material, "βTCP" only.

Further, although *Hubbard et al.* generally describes βTCP as a potential ceramic material that may be contained in the disclosed composition, *Hubbard et al.* does not teach the biodegradability of βTCP, nor any time period for the degradation. In fact, *Hubbard et al.* teaches away from this degradation, as it requires ***permanent*** implants. Accordingly, *Hubbard et al.* fails to teach the limitation of the present claims, "said microparticles are ***biodegradable***, once the implantation has been made into the fibrous tissue, within a period of ***from 2 to 36 months."***

Further, although *Hubbard et al.* describes each of hyaluronic acid and xanthan gum as potential polysaccharides, this reference does not teach the use of a combination of the two materials, namely the hyaluronic acid-based compound and the thixotropic compound as recited in the present claims. No specific compositions containing hyaluronic acid or a combination of any two or more polysaccharides are described in *Hubbard et al.*

Furthermore, *Hubbard et al.* does not teach the specific surface area of the ceramic compound, nor the amount of the microparticles as recited in the present claims.

Accordingly, *Hubbard et al.* fails to teach each and every element of the presently pending claims as required by *Verdegaal Bros. v. Union Oil Co. of California.* Reconsideration and withdrawal of this rejection, therefore, is respectfully

requested.

IV. At page 9 of the Official Action, claims 22-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hubbard et al. in view of Janas et al. (US Patent No. 6,451,059).

V. At page 11 of the Official Action, claims 27-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hubbard et al. in view of Draenert (US Patent No. 4,373,217).

VI. At page 13 of the Official Action, claims 31-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hubbard et al. in view of Gertzman et al. (US Patent No. 7,019,192).

Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)*, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc.* v. *Chugai Pharm. Co.*, 18 USPQ 1016, 1023 (C.C.P.A 1970). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494,

496 (C.C.P.A. 1970).

In the present application, a *prima facie* case of obviousness has not been established by the Examiner since none of the cited references, taken alone or in combination, teaches all of the limitations of the pending claims as required by *In re Wilson*.

Rejected claims 22-23, 27-28 and 31-33 have been cancelled in the present application. Pending claims 38 and 44 correspond to cancelled claims 22-23, pending claims 55 and 56 correspond to cancelled claims 27-28, and pending claims 51-53 and 66-68 correspond to cancelled claims 31-33. All of said pending claims, i.e., claims 38, 44, 51-53, 55, 56 and 66-68 are, directly or indirectly, dependent from claim 38 or claim 55, and thus, incorporate all the limitations of claim 38 or claim 55 as noted above.

Claims 38 and 55 were discussed in Section III, above, with regard to the anticipation rejection by *Hubbard et al.*, which is incorporated herein by reference in its entirety. To summarize, all of the pending claims necessarily require a "resorbable implant" comprising microparticles of βTCP which are biodegradable in the fibrous tissue within 2 to 36 months. In addition, the discussion of *Hubbard et al.* made in Section III, above, is also incorporated herein by reference in its entirety. To summarize, *Hubbard et al.* fails to teach all of the limitations of the pending claims. *Hubbard et al.* fails to teach the "resorbable implant" comprising the biodegradable ceramic material, βTCP, which is "biodegradable" in the fibrous tissue "within 2 to 36

months." In addition, *Hubbard et al.* fails to teach the vector fluid comprising hyaluronic acid-based compound and the biodegradable thixotropic compound with pseudoplastic properties as required by the pending claims. Further, *Hubbard et al.* fails to teach the surface area of the ceramic compound and the amount of the microparticles in the vector fluid as recited in claims 38 and 55, respectively.

None of Janas et al., Draenert and Gertzman et al., in combination with Hubbard et al., cures the deficiencies of Hubbard et al.

Janas et al. (US Patent No. 6,451,059) describes a hard tissue scaffold comprising a resorbable ceramic. *Janas et al.* is cited by the Examiner to cure the deficiency of *Hubbard et al.*, i.e., lacking the teaching of the surface area "0.5 m^2/g to 100 m^2/g," as required by claim 38, since this reference describes particles of ceramic tricalcium phosphate ($Ca_3(PO_4)_2$), with a BET surface area of 1.708 m^2/g. *See* Example 1.

Janas et al. teach the use of particles of tricalcium phosphate (with an initial surface area of 1.708 m^2/g) ***to prepare ceramic fibers and scaffolds, suitable for use in bone replacement***. Thus, *Janas et al.* fail to teach an implant comprising ***microparticles*** of tricalcium phosphate having a surface area of 0.5 to 100 m^2/g, as required by claim 38. As such, *Janas et al.* cannot cure the deficiency of *Hubbard et al.*, with regard to the surface area limitation.

Accordingly, *Hubbard et al.*, taken alone or in combination with *Janas et al.*, cannot render claims 38 and its dependent claim 44, which corresponds to rejected claims 22-23, now cancelled, obvious within the meaning of 35 U.S.C. §103(a).

Draenert (US Patent No. 4,373,217) describes an implantation material comprising a polymeric base of an acrylate, a polymethacrylate, a copolymer of an acrylate and a methacrylate or a mixture therefore, and 5-35% by weight of resorbable tricalcium phosphate of a particle size of 50-300 μm. This reference is cited by the Examiner to cure the deficiency of *Hubbard et al.* that it lacks the teaching of the amount "greater than 0 and less than 15%" of the microparticles in the vector fluid, as required by claim 55.

However, assuming *arguendo* that *Draenert* can cure the deficiency of *Hubbard et al.* with regard to the amount of the microparticles, *Draenert* cannot cure the other deficiencies of *Hubbard et al.*, as noted above. Not only does *Draenert* fail to teach or suggest the use of a hyaluronic acid-based compound and a biodegradable thixotropic compound as a vector fluid, but also *Draenert* fails to teach the surface area of the ceramic compound, as required by claim 38. *Draenert* also fails to teach the biodegradable time of the implant, as recited in claim 38.

In addition, *Draenert* relates to ***stable implantation materials, also known as bone cements*** which may be obtained "by mixing a special tricalcium phosphate in a specific amount and, above all, in an exactly defined particle size, to the conventional bone cements based on polyacrylates" (*see col. 1, lines 1 to 13 and* col. 2, lines 23-30). These stable implantation materials are used in bone replacement and bonding, and as prosthesis anchoring materials. Regarding the "exactly defined particle size" useful for obtaining the stable implants, *Draenert* at col. 2, lines 37-44,

requires the use of "tricalcium phosphate having a particle size of 50 μm to 300 μm". Further, col. 5, lines 5-6 of *Draenert* disclose that "Particles having a size of 80-200 μm are especially preferred." In contrast, the presently pending claims require a particle size of 10-80 μm, more specifically 15 to 50 μm as per present claim 39. Accordingly, similar to *Hubbard*, the particle size discussion in *Draenert* clearly teaches away from the present claims. **In fact, *the disclosures of Hubbard and Draenert actually reinforce each other in teaching away from the present claims, as both references relate specifically to permanent or stable implants, whereas the present claims are directed solely to resorbable implants*.**

Accordingly, *Hubbard et al.*, taken alone or in combination with *Draenert*, cannot render claim 55 and its dependent claim 56, which correspond to rejected claims 27-28, now cancelled, obvious within the meaning of 35 U.S.C. §103(a).

Gertzman et al. (US Patent No. 7,019,192) describes a formable ***bone composition*** for application to a bone defect site to promote new bone growth at the site which comprises a new bone growth inducing compound of demineralized lyophilized allograft bone particles. Further, *Gertzman et al.* describes that the carriers for the formable bone composition are preferably taken from higher molecular weight hydrogels such as Sodium Hyaluronate $6.6X10^5$ - $2.6X10^6$ Daltons and its derivatives. This reference is cited by the Examiner to cure the deficiency of *Hubbard et al.* regarding hyaluronic acid and its molecular weight of "greater than one million daltons" or "greater than one to five million daltons," as required by pending

claims 51-53 and 66-68.

However, assuming *arguendo* that *Gertzman et al.* can cure the deficiency of *Hubbard et al.* with regard to the hyaluronic acid and its molecular weight, *Gertzman et al.* cannot cure the other deficiencies of *Hubbard et al.*, as noted above. Not only does *Gertzman et al.* fail to teach or suggest the resorbable implant comprising βTCP which is biodegradable in the fibrous tissue within 2 to 36 months, but also *Gertzman et al.* fails to teach use of the hyaluronic acid compound in combination with a thixotropic compound (such as a xanthan-based compound or a cellulose derivative), as required by pending claim 38 and claim 55.

Accordingly, *Hubbard et al.*, taken alone or in combination with *Gertzman et al.*, cannot render claims 38 and 55 and their dependent claims 51-53 and 66-68, which correspond to rejected claims 31-33, now cancelled, obvious within the meaning of 35 U.S.C. §103(a).

As such, Applicants respectfully assert that nothing in *Hubbard et al.*, in combination with any of *Janas et al., Draenert* and *Gertzman et al.,* renders the pending claims obvious within the meaning of 35 U.S.C. §103. Therefore, reconsideration and withdrawal of the three rejections above is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance. Early notice to this effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

In the event this paper is not timely filed, applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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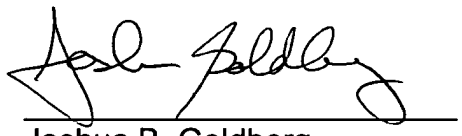

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